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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/103,745	06/24/1998	SUDHIR AGRAWAL	475.08.642CI	3401

7590 08/24/2005

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EXAMINER

SCHULTZ, JAMES

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/103,745

Applicant(s)

AGRAWAL, SUDHIR

Examiner

J. D. Schultz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 19 May 2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 1 July 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 19 May 2005 is acknowledged. However, applicant's most recent response of 19 May 2005 canceled the previously added claims which triggered the restriction requirement. The cancellation of these claims obviates the instant restriction requirement. While the instant restriction is accordingly no longer valid, it is noted that any future reintroduction of said canceled claims 6-15 would again subject these claims to restriction.

### ***Priority***

The priority of the instant application was amended on 30 April 2003 as follows: "This application claims the benefit of priority under 35 U.S.C. 119 of PCT/US97/16017, filed on

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September 10, 1997 which is a continuation-in-part of U.S.S.N. 08/711,568 filed on September 10, 1996, now U.S. Patent No. 5,856,462.”

This statement as recited is objected to because it claims only “priority” to PCT/US97/16018, but does not specify which type of priority, i.e., if it's a 35 USC 371 filing, a continuation, a divisional, or a CIP of the international application.

### ***Response to Arguments, Double Patenting***

Claims 1, and 3-5 are the rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,856,462 for the same reasons of record cited in the Office action mailed September 9, 1999. It is acknowledged that Applicant's response to the double patenting rejection of Sept. 9, 1999 indicated that, should any pending claims be indicated as allowable, applicant will file a Terminal Disclaimer disclaiming the portion of the term of the patent beyond the expiration date of U.S. Patent Number 5,856,462.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The invention of claim 3 is drawn to "A method for providing a CpG-containing phosphorothioate oligonucleotide with reduced splenomegaly and reduced depletion of platelets to a mammal..." it is unclear how an oligonucleotide can have reduced splenomegaly and reduced depletion of platelets, since these are considered characteristics of whole organisms, and not molecules.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook, who U. S. Patent Number 5,856,462.

The invention of the above claims is drawn to a composition comprising a phosphorothioate oligonucleotide that further comprises a modified CpG motif, wherein said modification is selected from the group consisting of alkylphosphonate, 2'-O, stereospecific phosphorothioate, phosphotriester, phosphoramidate, and 2'-5' CpG motifs. The invention is also drawn to methods of reducing the side effects of the administration of antisense oligos comprising administering antisense oligos which comprise the aforementioned CpG modifications.

Cook teaches compositions comprising a phosphorothioate oligonucleotide that further comprises a modified CpG motif, wherein said modification is selected from the group

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consisting of alkylphosphonate, 2'-O, stereospecific phosphorothioate, phosphotriester, and phosphoramidate CpG motifs. Although Cook contemplates the use of such compositions in methods of treating disease, Cook does not explicitly teach that such methods would reduce the side effects of the administration of antisense oligos. However, because both the instant method steps and those of Cook comprise the sole active step of administering the subject oligos, the method of Cook would thus be considered to have the inherent outcome of reducing side effects accordingly, Cook is thus considered to anticipate both the instant compound claims as well as the method claims.

### *Conclusion*

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

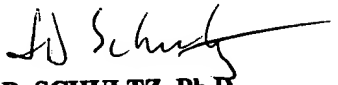
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problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JD Schultz, PhD

  
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